IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CLASSEN IMMUNOTHERAPIES, INC.,	*	
Plaintiff,	*	
v.	*	Civil Case No.: RWT-13-921
SHIONOGI, INC., ET AL.,	*	
Defendants.	*	

MEMORANDUM OPINION

Plaintiff Classen Immunotherapies, Inc. ("Classen") has sued Defendants Shionogi, Inc. ("Shionogi") and Merz Pharmaceuticals, LLC, ("Merz") for infringing two of Classen's patents under 35 U.S.C. § 271 and 35 U.S.C. § 154(d). Defendants have moved to dismiss Classen's Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Their motion will, as explained below, be granted.

The fundamental problem for Classen is that the actions of the Defendants complained of took place in a harbor made safe and immune from Classen's attacks by federal law. Moreover, Classen's attacks, even if unprotected by the safe harbor, also miss their mark.

Classen's infringement allegations must be dismissed under 35 U.S.C. § 271(e)(1), a safe harbor provision added by the Hatch-Waxman Act in 1984 that protects the use of patented inventions in activities "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). In addition, Classen's assertions under § 271 must be dismissed because some of the alleged steps of infringement occurred before the patents were issued, and Classen's § 154(d) allegations must be dismissed because Classen's patent applications are not "substantially

identical" to its issued patents. Finally, Merz is only alleged to have infringed one step of the patented processes at issue, and the fact that it only recently acquired a drug developed by Shionogi means that Classen's Complaint against this Defendant in particular must also be dismissed.

FACTUAL BACKGROUND[1]

I. Patents '069 and '639

Classen asserts that Defendants infringed two of its patents – U.S. Patent No. 7,984,069 ("'069") and U.S. Patent No. 7,653,639 ("'639"). Compl. ¶¶ 11-12, 15-16, ECF No. 1. The '069 patent application was published June 27, 2002, and the patent was issued July 19, 2011. ECF No. 1-5. The '639 patent application was published August 31, 2006, and the patent was issued January 26, 2010. ECF No. 1-4.

Each patent is titled "Computer Algorithms and Methods for Product Safety," and the claims[2] of each patent are quite similar. ECF Nos. 1-4, 1-5. The '069 patent contains two independent claims, the key claim being claim 1, as it is referenced directly or through incorporation by every other claim except for claim 50, the other independent claim. *See* ECF No. 1-5. The '639 patent has only one independent claim, claim 1. *See* ECF No. 1-4.

The first claim in each patent covers a multistep process (referred to as a "method" in each patent) that accesses and analyzes "adverse event data associated with [a] product or device" and "identif[ies] at least one ["new" or "previously unreported"] essential adverse event

[1] This section relies on facts stated in Plaintiff's Complaint (ECF No. 1) and on documents that may be considered at this motion to dismiss stage because they are a matter of public record of which the court may take judicial notice or are authentic and integral to the complaint. *Philips v. Pitt Cnty. Mem'l Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009); *Wittholn v. Fed. Ins. Co.*, 164 F. App'x 395, 396 (4th Cir. 2006) (noting the court's ability to consider "official public records"); *Walker v. Kelly*, 589 F.3d 127, 139 (4th Cir. 2009); *see E.I. du Pont de Nemours & Co. v. Kolon Industries, Inc.*, 637 F.3d 435, 448-49 (4th Cir. 2011).

[2] "[T]he claims of a patent define the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)) (internal quotation marks omitted).

associated with the product or device." ECF Nos. 1-5 at 18-19, 1-4 at 18. The claims define the essential adverse event as "one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device." ECF Nos. 1-5 at 18-19, 1-4 at 18. Claim 1 of the '069 patent also includes a step of "identifying at least one previously unreported method of use of the product or device associated with [the] identified essential adverse event" and "documenting inventorship of the" method identified. ECF No. 1-5 at 19.

In addition, both patents incorporate the creation of a "database" of "essential adverse event information" and the "commercializ[ation]" of either the "previously unreported proprietary method of using a product or device" ['069] or "the proprietary essential adverse event information stored" in the database ['639]. ECF Nos. 1-5 at 19, 1-4 at 19. Claim 1 of the '069 patent defines commercialization as "creating profit from . . . exclusive disclosure." ECF No. 1-5 at 19. Claim 1 of the '639 patent does not define commercialization but ties it to the "exclusive disclosure of the newly-identified proprietary essential adverse information which, once identified, must then accompany the product or device." ECF No. 1-4 at 19.

A federal court in the Central District of California recently examined both of these patents in *Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals*, describing them as follows:

> These two patents teach methods for generating, organizing, and commercializing 'adverse event' information associated with a product or device. Essentially, they describe a database management methodology for evaluating the efficacy of a therapeutic method and identifying its associated side effects.

Somaxon, Civil Case No. 2:12-cv-06643-GAF-PLA, Dkt. No. 43 at *1 (C.D. Cal. Apr. 11, 2013) (citations omitted), *aff'd per curiam without opinion*, No. 2013-1405, 2014 WL 185171 (Fed. Cir. Jan. 17, 2014).

II. Alleged Infringement of Patents '069 and '639

Classen alleges that Shionogi, previously known as Sciele Pharma, Inc. ("Sciele"),[3] and Merz infringed both the '639 and the '069 patents in violation of 35 U.S.C. §§ 271 and 281 and 35 U.S.C. § 154(d). Compl. ¶¶ 1, 5-6.[4]

According to Classen, Shionogi "manufactures and distributes . . . pharmaceutical products," including Robinul®, Robinul Forte®, and CUVPOSA®, that contain glycopyrrolate, a substance used to treat ulcers. Compl. ¶ 7. Classen alleges that "Sciele determined that the efficacy of glycopyrrolate can be affected by the timing of consumption of food, including the determination that glycopyrrolate should not be given between 1 hour before to 2 hours after a meal, and [it] protected this development through proprietary filings," including a number of patent applications. Compl. ¶ 8. Classen also asserts that sometime "[o]n or around August 27, 2012, Merz acquired the brand name CUVPOSA® for the liquid form of the glycopyrrolate drug from Shionogi," and that "CUVPOSA® has been commercially available since July 2010." Compl. ¶ 10.

A. Patent '069

Classen alleges that both Defendants have infringed the '069 patent "by commercializing information related to glycopyrrolate," Compl. ¶ 33, presumably in reference to the food effect disclosure. In particular, Defendants allegedly infringed the patented method of the '069 patent and "identif[ied] a food related, previously unreported essential adverse event associated with glycopyrrolate that is regulated by the FDA, and requires disclosure accompanying glycopyrrolate." Compl. ¶ 16. Shionogi supposedly "developed a dosage requirement for

[3] Sciele "was acquired by" Shionogi's "parent company" in 2008. (Compl. ¶¶ 5-6).

[4] For purposes of Defendants' Motion to Dismiss, the validity of these patents is assumed. A case pending before the Supreme Court could shed further light on the validity of patents like these. *See CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269 (Fed. Cir. 2013) *cert. granted*, 134 S. Ct. 734 (2013).

glycopyrrolate[,] . . . documented inventorship of the new dosage[,] and established a patent application and publication related to [the] new restricted use dosage." Compl. ¶ 16. The "new dosage requirement" was "commercialized" through "the requirement for the information[] to mandatorily accompany glycopyrrolate," Shionogi's efforts to obtain patent rights and sell "glycopyrrolate with labeling," and its "sale [of] the patent protected brand to Merz." Compl. ¶ 16. Classen asserts that Merz in particular "commercializes by continuing to seek . . . patent rights through continued pending patent applications, through maintaining and enforcing its patent rights[,] and through the sales of glycopyrrolate." Compl. ¶ 17.

B. Patent '639

Classen alleges that both Defendants have infringed the '639 patent "by commercializing information related to glycopyrrolate," Compl. ¶ 23, apparently referring to the impact of food consumption on the use of glycopyrrolate. In particular, Shionogi allegedly "accessed at least one adverse event data source[,] analyzed the adverse event data[,] and identified a food related adverse event associated with glycopyrrolate [that is] regulated by the FDA" and required to be disclosed "in a package insert or data sheet accompanying glycopyrrolate." Compl. ¶ 12. Classen claims that Shionogi "commercialized the proprietary information by obtaining patent protection and advocating the requirement of disclosure of the information accompanying glycopyrrolate." Compl. ¶ 12. Shionogi also allegedly "continued to commercialize through the . . . sales of glycopyrrolate with labeling . . . and the sale of the patent protected brand to Merz." Compl. ¶ 12. According to Classen, the act of selling glycopyrrolate products "with labeling [that] notifies the user of the food effect adverse event" infringes the '639 patent. *See* Compl. ¶ 13.

III. Procedural History

Plaintiff Classen filed its initial Complaint against Defendants Shionogi and Merz in this Court on March 27, 2013. ECF No. 1. On May 31, 2013, Defendants filed a Motion to Dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). ECF No. 19. Plaintiff filed an Opposition on June 17, 2013, ECF No. 23, and Defendants filed a Reply on July 3, 2013, ECF No. 24. This Court held a hearing on Defendants' motion on November 1, 2013.

STANDARD OF REVIEW

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of the complaint. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999). A court must consider all well-pleaded allegations in a complaint as true, *see Albright v. Oliver*, 510 U.S. 266, 268 (1994), and must construe factual allegations "in the light most favorable to the plaintiff," *see Lambeth v. Bd. of Comm'rs of Davidson Cnty.*, 407 F.3d 266, 268 (4th Cir. 2005). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)); *see also Simmons v. United Mortg. & Loan Invest., LLC*, 634 F.3d 754, 768 (4th Cir. 2011) ("On a Rule 12(b)(6) motion, a complaint must be dismissed if it does not allege enough facts to state a claim to relief that is plausible on its face.") (internal quotation marks and emphasis omitted). "Thus, '[i]n reviewing a motion to dismiss an action pursuant to

Rule 12(b)(6) . . . [a court] must determine whether it is plausible that the factual allegations in the complaint are enough to raise a right to relief above the speculative level.'" *Monroe v. City of Charlottesville*, 579 F.3d 380, 386 (4th Cir. 2009) (quoting *Andrew v. Clark*, 561 F.3d 261, 266 (4th Cir. 2009)).

The Federal Circuit has noted that Federal Rule of Civil Procedure Form 18 supplies an example of what is required to adequately plead a "complaint for direct patent infringement." *R+L Carriers, Inc. v. DriverTech LLC*, 681 F.3d 1323, 1334 (Fed. Cir. 2012). According to the Federal Circuit, the pleading requirements of Form 18 include the following:

> (1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent 'by making, selling, and using [the device] embodying the patent'; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages.

Id. (quoting *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1357 (Fed. Cir. 2007)). The Federal Circuit has also acknowledged that "an implausible claim for patent infringement rightly should be dismissed," and that "[t]he touchstones of an appropriate analysis under Form 18 are notice and facial plausibility." *K-Tech Telecomms., Inc. v. TimeWarner Cable, Inc.*, 714 F.3d 1277, 1284, 1286 (Fed. Cir. 2013).

ANALYSIS

I. The Safe Harbor Provision of 35 U.S.C. § 271(e) Protects Defendants from Allegations of Infringement

A. The Safe Harbor Provision May Be Examined at the Motion to Dismiss Stage

The safe harbor provision in 35 U.S.C. § 271(e)(1) may properly be considered at the motion to dismiss stage, even if it is viewed as an affirmative defense. Previous district court decisions have found that the "section 271(e) safe harbor provision is an affirmative defense." *Somaxon*, at *3 n.1 (citing *Amgen, Inc. v. F. Hoffman-LaRoche, Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass.

2006)). However, even if the safe harbor is treated as an affirmative defense and not "a part of the statutory definition of infringement," *see Amgen, Inc.*, 456 F. Supp. 2d at 273 (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 109 (D. Mass. 1998)), the safe harbor may still be examined at this stage. The *Somaxon* court explained that while it is a "general rule [that] an affirmative defense may not serve as a basis for dismissal under Rule 12(b)(6) . . . the Court may consider affirmative defenses on a motion to dismiss where they are clear from the face of the complaint." *Somaxon*, at *3 n.1 (citing *Alphamed Pharm. Corp. v. Arriva Pharm., Inc.*, 391 F. Supp. 2d 1148, 1160 n.6 (S.D. Fla. 2005)). Here, as in *Somaxon*, Classen's Complaint clearly implicates the safe harbor provision of § 271(e)(1), as it asserts that the Defendants violated its '069 and '639 patents by improperly "commercializing" information required to be disclosed pursuant to the federal pharmaceutical regulatory process described in § 271(e)(1).[5]

B. Application of the Safe Harbor

"It is generally an act of patent infringement to 'mak[e], us[e], offe[r] to sell, or sel[l] any patented invention . . . during the term of the patent therefor.'" *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195 (2005) (quoting 35 U.S.C. § 271(a)). This protection is limited, however, by the "safe harbor" provision contained in 35 U.S.C. § 271(e)(1) which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This provision shields drug manufacturers from patent infringement liability for using patented inventions in activities that are "reasonably related to the development and submission of"

[5] *See supra* Factual Background; *infra* Analysis Part I.B.

information pursuant to the federal regulatory process of pharmaceuticals. *Merck KGaA*, 545 U.S. at 202. Congress enacted this provision of the Hatch-Waxman Act in 1984 to "'balance the need to stimulate innovation against the goal of furthering the public interest.'" *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1354 (Fed. Cir. 2012) (quoting H.R. Rep. 98-857, pt. 2, at 2714 (1984), 1984 U.S.C.C.A.N. 2686, 2714).

The expansive text of § 271(e)(1) and the decision in *Momenta* instruct that the safe harbor shelters the Defendants from Classen's allegations of infringement. The word "invention" in § 271(e)(1)'s phrase "patented invention" is defined under Title 35 of the U.S. Code to "mean[] invention or discovery." 35 U.S.C. § 100(a). Thus, "[t]he phrase 'patented invention' . . . include[s] all inventions, not drug-related inventions alone." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665-78 (1990) (extending coverage to medical devices); *Momenta*, 686 F.3d at 1351-52 (extending coverage to the use of a patented "method for analyzing [a drug] sample" for the existence of a certain type of sugar).[6] Accordingly, Classen's '069 and '639 patents generally qualify as "patented inventions" under § 271(e)(1), and their validity is assumed for purposes of the Defendants' motion.

Activities carried out to satisfy FDA requirements fall within the safe harbor. The use of a patented invention qualifies for safe harbor protection "[a]s long as the accused infringer 'has a reasonable basis for believing' that use of the patented invention might yield information that 'would be appropriate to include in a submission to the FDA.'" *Momenta*, 686 F.3d at 1356-57 (quoting *Merck KGaA*, 545 U.S. at 207). Actual submission of information under a federal regulatory scheme is not required. *Momenta*, 686 F.3d at 1356-57 ("[T]he requirement to

[6] Although the Supreme Court has stressed the importance of symmetry in the statutory scheme's coverage of patented products that both retain the benefit of a provision in 35 U.SC. § 156 (section 201 of the Hatch-Waxman Act) and the disadvantage of § 271(e)(1) (section 202 of the Hatch-Waxman Act), *see Eli Lilly*, 496 U.S. at 669-74, the Federal Circuit has clarified that "'statutory symmetry is preferable but not required.'" *Momenta*, 686 F.3d at 1361 (quoting *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997)).

maintain records for FDA inspection satisfies the requirement that uses be reasonably related to the development and submission of information to the FDA.").

The key inquiry for safe harbor purposes is whether the defendant's actions were "carried out to 'satisfy the FDA's requirements.'" *Momenta*, 686 F.3d at 1359. Because the text of § 271(e)(1) "is not restricted to pre-approval activities," § 271(e)(1) also applies to post-FDA approval activities falling within its scope. *Momenta*, 686 F.3d at 1358-59; *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, Civil No. WDQ-04-3521, 2013 WL 5934055, at *4 (D. Md. Oct. 31, 2013) (noting that *Momenta* "rejected any 'artificial' distinction in the safe harbor's coverage between pre-FDA approval and post-approval activities"). Finally, as long as the safe harbor applies, it "does not look to the underlying purposes or attendant consequences of the activity." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) ("In other words, the statutory language allows [defendant] to use its data from the tests for more than FDA approval.").

Two prior patent infringement cases brought by Classen provide guidance here. In 2006, another court in this district rejected Classen's allegations that a pharmaceutical company had infringed "patented methods for identifying and commercializing new uses of existing drugs." *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F. Supp. 2d 621, 623 (D. Md. 2006). In that case, "the results of [a] study were submitted to the FDA in [the defendant's] Citizen Petition and labeling supplement to its [New Drug Application]," thus shielding the defendant from Classen's allegations under § 271(e)(1). *Id.* at 625.

Last year, the *Somaxon* court dismissed Classen's accusations that a drugmaker had infringed the same two patents at issue in this case, holding that "the creation of a label disclosing [a drug's] adverse events is clearly 'reasonably related' to obtaining FDA approval."

Somaxon, at *5.[7] The court explained that "the FDA specifically requires submission of draft labeling language as part of its approval process for new drugs," and that "21 C.F.R. § 314.50, which governs the content and format of applications for FDA approval to market a new drug, provides that the summary of the application is to include '[t]he proposed text of the labeling.'" *Id.* (quoting 21 C.F.R. § 314.50(c)(2)(i)). In addition, "a manufacturer may even have to provide '[s]amples of the finished market package, if requested by FDA.'" *Id.* (quoting 21 C.F.R. § 314.50(e)(ii)).

Classen's charges of infringement are clearly foreclosed by § 271(e)(1). The processes embraced by the '069 and '639 patents are inherently tied to a regulatory approval process, as they require that the novel "essential adverse event" described in each patent be "one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device." ECF Nos. 1-5 at 18-19, 1-4 at 18. Classen's Complaint alleges that both of its patents were infringed when Shionogi performed the steps of each patent, including the step of "identif[ying] a food related . . . adverse event associated with glycopyrrolate that is regulated by the FDA, and requires disclosure accompanying glycopyrrolate." Compl. ¶ 16 (alleging infringement under patent '069 and echoing the same allegation under patent '639[8]). As a matter of law, Shionogi's actions are protected by the safe harbor of § 271(e)(1). As the *Somaxon* court concluded, the "adverse event data . . . collected and eventually used to create . . . patented labels was generated as part of the FDA approval process and therefore falls within the purview of the safe harbor." *Somaxon*, at *7.

[7] This decision was affirmed without opinion by the Court of Appeals for the Federal Circuit on January 17, 2014. *Classen Immunotherapies, Inc. v. Somaxon Pharmaceuticals*, No. 2013-1405, 2014 WL 185171 (Fed. Cir. Jan. 17, 2014).

[8] Classen alleges that Shionogi infringed patent '639 by performing the steps of the patented method, including the step of "identif[ying] a food related adverse event associated with glycopyrrolate regulated by the FDA requiring disclosure in a package insert or data sheet accompanying glycopyrrolate." Compl. ¶ 12.

Classen's attempts to avoid the safe harbor run aground under *Momenta*. Classen argues that its patent infringement allegations are not barred by § 271(e)(1) because its patents include claims that are "commercialization steps which are not used to develop or submit information to the FDA." *See, e.g.*, Opp'n at 2, ECF No. 23. Classen admits that "[c]linical trials generate information, such as the proper manufacturing method or the proper dosage requirements or methods of treatment," and that "[t]his information is submitted to the FDA," and "thus the generation and use of this information during the clinical trials . . . is protected." Opp'n at 3, ECF No. 23. Nevertheless, Classen asserts that "[t]he subsequent generation and/or use of this same information during commercial sales is not protected." Opp'n at 3, ECF No. 23. Classen's argument rests on its theory that "the safe harbor ***expires*** after FDA approval is obtained. If it did not, no pharmaceutical patents would ever be enforceable." Opp'n at 3, ECF No. 23. Classen relies on *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) for the proposition that the safe harbor "'does not apply to information that may be routinely reported to the FDA, ***long after*** marketing approval has been obtained.'" Opp'n at 27, ECF No. 23 (quoting *Biogen*, 659 F.3d at 1070 and adding emphasis). However, the later decision in *Momenta* clarified that there is no pre/post FDA approval dichotomy under the safe harbor provision. To the extent that there is any tension between *Biogen* and *Momenta*, *Momenta* controls, as it is the more recent Federal Circuit decision.[9] Thus, § 271(e)(1) precludes Classen's infringement claims from proceeding.

[9] Classen's attempts to distinguish a "process" or "method" claim from an "apparatus" claim are also not persuasive. *See* Opp'n at 15-16, ECF No. 23. Defendants argue convincingly that because the independent claims in each patent refer to a "method" of discovering adverse event information, and the "apparatus" claims referenced by Plaintiff are contained in *dependent* claims of the patents, the "method steps of the independent claims . . . namely claim 1 of the respective . . . patents, must be practiced by Defendants in order to infringe the dependent claims." Reply at 14, ECF No. 24 (citing *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1358 (Fed. Cir. 2007) for support); *see also Monsanto*, 503 F.3d at 1358 (holding that a dependent claim incorporated by reference the process of an independent claim). In addition, allegations of product infringement under a patent that addresses the process by which the product is created incorporate that patent's process as a limitation to the product. *Atlantic Thermoplastics*

II. Classen's § 271 Claims Also Fail Because Some of the Alleged Steps of Infringement Occurred Pre-Patent Issuance

Classen's allegations under § 271 must also be dismissed because not all of the alleged steps of infringement transpired after the issuance of Classen's patents, and because § 154(d) and § 271 may not be combined to create a single cause of action. Section 271 states that "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention *during the term of the patent therefor*, infringes the patent." 35 U.S.C. § 271(a) (emphasis added). When a "method" or "process" patent like the '069 or '639 patents are at issue, each of the steps of the patented method must occur post-patent issuance for infringement under § 271 to occur. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1360 (Fed. Cir. 2007) (because three of four steps of an allegedly infringed patented process took place before the patent was issued, § 271 did not apply); *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1194-96 (Fed. Cir. 1996) (holding that indirect infringement under §271(b) could not occur if some of the infringement occurred pre-patent issuance); *Baseball Quick, LLC v. MLB Advanced Media, L.P.*, No. 11-1735, 2012 WL 1071230, at *4 (S.D.N.Y. Mar. 30, 2012) (invoking *Monsanto*). Plaintiff concedes that "Defendant Shionogi performed some steps of the method after publication and some steps after issuance." Opp'n at 7, ECF No. 23. Thus, Plaintiff concedes that § 271 does not apply because not all of the steps were performed after issuance.

Plaintiff nevertheless argues that even though some steps were performed pre-patent issuance, it should be able to combine sections 154(d) and 271 into a single cause of action that would cover pre and post patent issuance actions. Classen offers no support for such a proposition, and it must be rejected. Classen asserts:

Co. v. Faytex Corp., 970 F.2d 834, 846-47 (Fed. Cir. 1992) ("process terms in product-by-process claims serve as limitations in determining infringement.").

> There is no dispute that the activities could be combined and accused if they occurred entirely **before** issuance of the patent or if they occurred entirely **after** issuance. Defendants' proposition, that because the date of issue of the patent happened to fall between two of the steps, Shionogi's activities are protected from any accusations of infringement, is wrong and unsupported.

Opp'n at 7-8, ECF No. 23. However, Plaintiff fails to cite any cases in support of its argument that the two sections may be combined. The statutory language of each section does not support Plaintiff's argument: § 271 applies to actions taken "during the term of the patent," while § 154(d) applies to actions "during the period beginning on the date of publication of the application . . . and ending on the date the patent is issued." 35 U.S.C. § 271(a); 35 U.S.C. § 154(d)(1). Thus, the two sections cannot be combined to create a super cause of action. *See Somaxon*, at *8-9 ("Infringement is not, as Classen suggests, determined by combining the relevant time period of these provisions." (internal quotation marks omitted)). Therefore, even without the protection of the safe harbor, Classen's § 271 allegations miss the mark.

III. Classen's § 154(d) Claims Also Fail Because its Patent Applications Were Not Substantially Identical to its Issued Patents

Classen's allegations under § 154(d) must also be dismissed because the published applications for the '069 and '639 patents were not substantially identical to the patents that ultimately issued. Section 154(d), added by Congress in 1999, *see* Pub. L. No. 106-113, 113 Stat. 1501A-564, provides provisional patent rights for the time period "beginning on the date of [the patent application's] publication" and "ending on the date the patent is issued." 35 U.S.C. § 154(d). However, to be an actionable claim, (1) the alleged infringer must have had "actual notice of the published patent application" and (2) the "invention as claimed in the patent" must be "substantially identical to the invention as claimed in the published patent application." 35 U.S.C. § 154(d).

When a published patent application's claims are amended such that their scope is changed, the patent is no longer "substantially identical" to its application. *See Icon Outdoors, LLC v. Core Res., Inc.*, Civil Action No. RDB-11-2967, 2013 WL 2476392, at *14-15 (D. Md. June 7, 2013) (holding that a change from "waterproof *or* windproof" to "waterproof *and* windproof" in a claim describing the material of "the upper portion of [a] hunting garment" was a "substantive change" precluding the application of § 154(d)). "Although not a *per se* rule, 'it is difficult to conceive of many situations in which the scope of a rejected claim that became allowable when amended is not substantively changed by the amendment.'" *Pandora Jewelry, LLC v. Chamilia, LLC*, Civil No. CCB-06-600, 2008 WL 3307156, at *9 (D. Md. Aug. 8, 2008) (quoting *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1348 (Fed. Cir. 1998)).

Both the '069 and the '639 patents underwent enough changes from application to issuance that § 154(d) simply does not apply.[10] The '069 patent application, published on June 27, 2002, *see* ECF Nos. 19-7, 1-5, lacks independent claim language tying the patented process to a regulatory process – this language was later added to overcome rejections by the United States Patent and Trademark Office, *see* ECF Nos. 19-7 at 18-25; 19-9 at 2, 16-19 (adding the language "wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device"). Because the published application lacks a comparable independent claim incorporating a regulatory process, s*ee* ECF No. 19-7 at 18-25, this added limitation to the issued patent narrows the scope of the claim and the patent, thus preventing Classen from invoking § 154(d). The '639 patent application, published on August 31, 2006, lacks any independent method claims, *see* ECF Nos.

[10] The Court may consider public records of these patents' prosecution history as documents appropriate for judicial notice. *See supra* note 1. A determination of whether the patent applications were "substantially identical" to the issued patents is also permissible at this stage because "[w]hether the patent and published application are substantially identical is a question of law." *Prestige Pet Prods., Inc. v. Pingyang Huaxing Leather & Plastic Co. Ltd.*, 767 F. Supp. 2d 806, 812 (E.D. Mich. 2011).

1-4, 19-10 at 19-21, while claim 1 of the issued patent is an independent method claim, ECF No. 1-4 at 18-19. The '639 application also lacks language found in the issued patent binding claim 1 to a regulatory process. *See* ECF Nos. 19-10 at 19-21, 1-4 at 18-19. Thus, the applications for the '069 and '639 patents are not "substantially identical" to the patents issued, and § 154(d) simply does not apply.

IV. Classen's Allegations Against Merz Fail Because Merz Is Only Alleged to Have Conducted One Step of the Patented Process

Finally, Classen's claims against Merz must be dismissed because Merz did not commit the acts required to find it liable under § 154(d) or § 271. Classen alleges in its Complaint that "[o]n or around August 27, 2012, Merz acquired the brand name CUVPOSA® for the liquid form of the glycopyrrolate drug from Shionogi." Compl. ¶ 10. Consequently, Merz is not alleged to have committed any pre-patent issuance infringement under § 154(d), as patent '069 was issued in 2011 and patent '639 was issued in 2010. Merz also cannot be liable for infringement under § 271 because Classen concedes that certain steps of its patents were infringed pre-patent issuance. *See supra* Analysis Part II. In addition, Merz is only accused of activities related to "commercialization." *See* Compl. ¶¶ 10, 17, 23.[11] Thus, Classen fails to allege that Merz has undertaken all of the steps required to infringe its patented methods, and all charges of infringement against Merz must be dismissed.

CONCLUSION

The Defendants are fully shielded from Classen's claims by the safe harbor, and, even if not, the claims fall far wide of the mark. Accordingly, the Court will grant the Defendants'

[11] Classen also avers that Merz infringed the '639 and '069 patents by infringing "apparatus" and "product"/ "kit" claims. Compl. ¶ 26, 27, 36, 37. However, for the reasons stated in *supra* note 9, allegations of apparatus/product/kit infringement of dependent claims incorporate by reference the method/process of the independent claims upon which they rely, thus requiring all of the steps of the method to have been infringed.

Motion to Dismiss [ECF No. 19] and dismiss the Complaint [ECF No. 1]. A separate Order follows.

Date: January 28, 2014

/s/
ROGER W. TITUS
UNITED STATES DISTRICT JUDGE